

REMARKS

Claims 1 and 4-8 are presently pending and under consideration.

Applicants thank the Examiner for informing them that the PALM system does not reflect the Power of Attorney changes made in the instant application. For the Examiner's records, Applicants have attached copies of the Election and Power of Attorney, Revocation of Power of Attorney, and Change of Correspondence Address filed in the instant application, as well as a copy of the Notice of Acceptance of Power of Attorney mailed October 10, 2003.

Claims 1 and 4-7 stands rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent Application Publication No. 2003/0165807 to Isfort *et al.* (hereinafter "Isfort *et al.*"), while claim 8 stands rejected under 35 U.S.C. §103(a) as obvious over Isfort *et al.* The Examiner has maintained these rejections for reasons of record. Specifically, the Examiner asserts that Isfort *et al.* disclose a sequence of urocortin II (SEQ ID NO:43; page 4, Table I), which is 100% identical to the amino acid sequence of SEQ ID NO:11 of the claimed invention. The Examiner further asserts that Isfort *et al.* indicate that urocortin II was cloned from *Mus musculus* and, therefore, meets the limitations of claims 4-7. In addition, the Examiner asserts that although Isfort *et al.* do not expressly disclose transfection of *E. coli* cells with a vector comprising DNA encoding urocortin II, it would have been *prima facie* obvious to a person of ordinary skill to modify the disclosure of Isfort *et al.* and propagate the DNA encoding urocortin II in *E. coli*.

Applicants respectfully traverse these rejections and submit that Isfort *et al.* is not prior art under Section 102(e). Specifically, Isfort *et al.* was not published before invention of the claimed subject matter by Applicants and, thus, cannot serve as a Section 102(e) reference for purpose of novelty or under Section 103(a) with regard to obviousness. Rather, Applicants submit that they possessed the presently claimed invention at least as early as February 27, 2001, which is prior to the March 6, 2001 priority filing date of Isfort *et al.* To evidence this date, Applicants submit herewith a Declaration Under 37 C.F.R. § 1.131 executed by all of the inventors of the instant application (titled and referred to herein as "Combined Rule 131/132 Declaration").

Applicants note that the content of this Combined Rule 131/132 Declaration is the same as that of the previously submitted Combined Rule 131/132 Declaration, which was considered ineffective to overcome Isfort *et al.* solely for procedural reasons, since it was not executed by all of the inventors as required by 37 C.F.R. § 1.131(a).

The Combined Rule 131/132 Declaration at paragraphs 3-6 establishes that the article entitled, "Urocortin II: A member of the corticotropin-releasing factor (CRF) neuropeptide family that is selectively bound by type 2 CRF receptors," published in *Proc. Natl. Acad. Sci.* 98:2843-2848 on February 27, 2001 (hereinafter referred to as "Reyes *et al.*"), describes the polypeptide sequence of murine urocortin II, including the peptide coding region (Fig. 1), and represents the work of the inventors, as acknowledged by the Examiner in the Final Office Action mailed April 27, 2004. Therefore, Reyes *et al.* antedates Isfort *et al.* by establishing actual reduction to practice of the claimed invention by the inventors, at least as early as its publication date of February 27, 2001 (which date is prior to the March 6, 2001 Section 102(e) date of Isfort *et al.*).

Accordingly, in view of the above remarks and the properly executed Combined Rule 131/132 Declaration submitted herewith, Applicants respectfully submit that Isfort *et al.* has been antedated and request that both the novelty and obviousness rejections premised thereon be withdrawn.

Applicants respectfully submit that claims 1 and 4-8 are in condition for allowance. However, should any further issue require attention, the Examiner is requested to contact the undersigned at (206) 622-4900.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



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Registration No. 33,507

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Enclosures:

- Combined Rule 131/132 Declaration
- Copy of Election and Power of Attorney
- Copy of Revocation of Power of Attorney
- Copy of Change of Correspondence Address
- Copy of Acceptance of Power of Attorney

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Wylie W. Vale, Jr., et al.  
Application No. : 09/919,473  
Filed : July 31, 2001  
For : Urocortin Proteins and Uses Thereof

Examiner : Dr. Olga Chernyshev  
Art Unit : 1646  
Docket No. : 690068.578

Commissioner of Patents  
Washington, DC 20231

COMBINED RULE 131/132 DECLARATION  
OF WYLIE W. VALE, JR., TERESA M. REYES, PAUL E. SAWCHENKO,  
JEAN E. RIVIER, KATHY A. LEWIS, JOHN B. HOGENESCH,  
JOAN M. VAUGHN, AND MARILYN H. PERRIN

Sir:

We, Wylie W. Vale, Jr., Teresa M. Reyes, Paul E. Sawchenko, Jean E. Rivier, Kathy A. Lewis, John B. Hogenesch, Joan M. Vaughn, and Marilyn H. Perrin hereby declare that:

1. We are co-inventors of the subject matter disclosed and claimed in the above-referenced patent application ("the subject application").

2. We have reviewed the Office Action dated October 30, 2003 in the subject application, including the rejections under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a) related to U.S. Patent Application Publication No. 2003/0165807 ("Isfort *et al.*") and provide this Declaration for the purpose of demonstrating that we, the co-inventors, had actually reduced the presently claimed invention to practice in this country prior to the March 6, 2001 priority filing date of Isfort *et al.*

3. We have reviewed the publication, Reyes *et al.*, *Proc. Natl. Acad. Sci.* 98:2843-2848 (February 27, 2001) ("Reyes *et al.*"), which describes work of the co-inventors presently claimed in the subject application. In light of this review, we readily

conclude that we (*i.e.*, the co-inventors) conceived and reduced to practice the presently claimed invention prior to March 6, 2001.

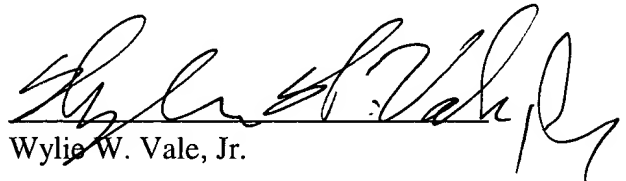
4. In support of this conclusion, we note that the manuscript that resulted in the Reyes *et al.* publication was contributed to P.N.A.S. on December 28, 2000, and that the Reyes *et al.* paper was subsequently published on February 27, 2001.

5. Accordingly, the subject matter disclosed and claimed in the subject application (*i.e.*, mouse urocortin polypeptides) was reduced to practice prior to the filing date of Isfort *et al.* - that is, prior to March 6, 2001.

6. We further submit that the co-inventors named in the subject application are the only inventors of the information set forth in Reyes *et al.* and claimed in the subject application, and that Reyes *et al.* co-authors K.S. Kunitake, C.A. Arias and J. Gulyas were working under the direction and supervision of one or more of the co-inventors. Therefore, Reyes *et al.* represents the work of the inventors named in the subject application and not the work of another.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the captioned patent application or any patent issued therefrom.

6/1/04  
Date

  
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6/3/04  
Date

  
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June 1, 2004  
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June 1, 2004  
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